AMENDMENTS TO THE CLAIMS

1. – 66. (Cancelled)

67. (currently amended) A process for the preparation of a concentrated~~, sterile injectable solution containing~~pharmaceutical composition of docetaxel comprising the following steps:

a) obtaining an anhydrous form of docetaxel in which the water content is ~~lower than~~ from 0.08 to 0.12% w/w, by the substeps:

a)(i) the hydrated docetaxel, in a solvent or in a chemically inert solvent mixture that forms an azeotrope with water and is of sufficient polarity to effect complete solubilization of the docetaxel, said solvent being selected from the group consisting of linear or branched alcohols, organic acids, halogenated solvents, and an aromatic solvent;

a)(ii) removing the water of hydration contained in the mixture (i) by azeotropic distillation at a temperature between -20 and 40°C and at a pressure between <0.001 and ~~780~~800 mm Hg, ~~preferably, between 1.0 and 20.0 mm Hg,~~ until the water content is ~~lower than~~ from 0.08 to 0.12% w/w;

b) adding an acid, selected from the group consisting of tartaric acid, ascorbic acid, citric acid and acetic acid~~, as a stabilizing agent,~~ to polysorbate 80, under an atmosphere of nitrogen, in a sufficient quantity to adjust the pH in the range of 3.0 to 6.5;

c) slowly adding ~~amorphous~~ anhydrous solid docetaxel, obtained by ~~steps described in~~ the process comprising a)(i) and a)(ii) ~~and that is free of ethanol~~ and from which alcoholic solvents have been removed, to the resulting solution of the step (B), under agitation and a nitrogen atmosphere, until the docetaxel is completely solubilized and a transparent solution is formed, in which the concentration of the docetaxel in its anhydrous form in the polysorbate 80, is in the range from ~~11 to~~1 to 100 mg/ml; and

d) filtering the concentrated solution obtained in c) by passage through a sterilizing membrane having a porosity ~~less than or equal~~ from 0.22 to 0.45 μm, to obtain a concentrated~~, sterile injectable solution~~pharmaceutical composition of docetaxel.

68. (Previously presented) The process according to claim 67 wherein an anhydrous solvent or a mixture of solvents is used in steps a)(i) and a)(ii).

69. (Currently amended) The process according to claim 67 wherein the solvents employed in the steps a)(i) and a)(ii) are a short chain linear or branched alcohol~~; a halogenated solvent or an aromatic solvent~~.

70. (Previously presented) The process according to claim 69 wherein the solvent employed is a short chain linear or branched alcohol.

71. (Previously presented) The process according to claim 70 wherein the alcohol employed is ethanol.

72. (Previously presented) The process according to claim 67 where in the step a), the starting docetaxel form contains 0.13 to 6.27% w/w of water, the solvents employed in the steps a)(i) and a(ii) are absolute ethanol and anhydrous toluene in a relative proportion of 1:9, and step a)(ii) is performed at a pressure between <0.001 and 100 mm Hg.

73. (Previously presented) The process according to claim 67 wherein the docetaxel employed as raw material in step a) is (2R,3S) 4-acetoxy-2-α-benzoyloxy-5β-20-epoxy-1,7-β-10-β-tri-hydroxy-9-oxo-tax-11-en-13α-yl 3-tert-butoxycarbonylamino-2-hydroxy-3-phenylpropionate, in its hydrated form, in which the amount of hydration water is 0.13 to 6.27% w/w.

74. (Previously presented) The process according to claim 67 wherein the docetaxel employed as the raw material in step a) is (2R,3S) 4-acetoxy-2-α-benzoyloxy-5β-20-epoxy-1,7-β-10-β-tri-hydroxy-9-oxo-tax-11-en-13α-yl 3-tert-butoxycarbonylamino-2-hydroxy-3-phenylpropionate •3 H_20, in which the amount of hydration water is 6.27% w/w.

75. (Currently amended) The process according to claim 67 wherein the docetaxel obtained at the end of the step a) is (2R,3S) 4-acetoxy-2-α-benzoyloxy-5β-20-epoxy-1,7-β-10-β-tri-hydroxy-9-oxo-tax-11-en-13α-yl 3-tert-butoxycarbonylamino-2-hydroxy-3-phenylpropionate, in which the water content is in the range of ~~0.00 to~~ 0.08 to 0.12% w/w.

76. (Previously presented) A process according to claim 67 wherein the final concentration obtained in the concentrated solution containing (2R,3S) 4-acetoxy-2-α-benzoyloxy-5β-20-epoxy-1,7-β-10-β-tri-hydroxy-9-oxo-tax-11-en-13α-yl 3-tert-butoxycarbonylamino-2-hydroxy-3-phenylpropionate, docetaxel, is from 1 to 100 mg of the active principle, on an anhydrous basis, for each mL of the polysorbate 80.

77. (Currently amended) The process according claim 67 wherein the acid ~~stabilizing agent~~ is added to the polysorbate 80 in an amount effective to adjust the pH of the pharmaceutical formulation in the range from 3.0 to 4.5.

78. (Currently amended) The process according claim 67 wherein the ~~stabilizing agent~~ acid is ascorbic acid.

79. (Currently amended) The process according claim 77 wherein the ~~stabilizing agent~~ acid is ascorbic acid.

80. (new) A process for preparing a pharmaceutical composition of docetaxel comprising:

adding solid anhydrous docetaxel, from which alcoholic solvent has been removed, to a polysorbate, and

adjusting the pH to a range from 3.5 to 6.5.

81. (new) The process of claim 80, in which the pH is adjusted with ascorbic acid, tartaric acid, citric acid or acetic acid.

82. (new) The process of claim 80 in which the pH is adjusted with tartaric acid or ascorbic acid.

83. (new) The process of claim 80 in which the polysorbate is polysorbate 80.

84. (new) The process of claim 80 in which the pH of the polysorbate is adjusted to a range of 3.5 to 6.5 prior to adding the solid anhydrous docetaxel.

85. (new) The process of any one of claims 80 to 84 in which the water content of the solid, anhydrous docetaxel is from 0.08 to 0.12% w/w.